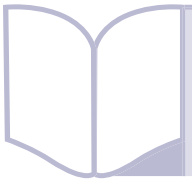
News and Views From the Literature



Pelvic Organ Prolapse

Pelvic Surgeons Caught in the Meshes of the Law

Toyohiko Watanabe, MD, PhD,[1] Michael B. Chancellor, MD[2]
[1]Department of Urology, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama City, Okayama, Japan; [2]Department of Urology, William Beaumont Hospital, Royal Oak, MI

[*Rev Urol.* **2012;14(1/2):35-36 doi: 10.3909/riu0543**]

In 2008, the US Food and Drug Administration (FDA) issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

The FDA issued an update on July 13, 2011, noting that serious complications associated with surgical mesh for transvaginal repair of POP are not rare and that it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair—and it may expose patients to greater risk.[1]

In 2008, the number of adverse events (AEs) reported to the FDA for surgical mesh devices used to repair POP and SUI for the 3-year period from 2005 to 2007 was over 1000. About 300,000 women in the United States had POP surgeries in 2010, including more than 70,000 who received vaginal meshes. From January 2008 through December 2010, the FDA received 2874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1503 reports associated with POP repairs and 1371 associated with SUI repairs. Although it is common for AE reporting to increase following an FDA safety communication, the FDA stated that there is concern about the number of AEs reported.

The most frequent complications reported to the FDA include mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems. The FDA stated that their literature review found that erosion of mesh through the vagina is the most commonly reported mesh-related complication. Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in AE reports submitted to the FDA since 2008. Mesh contraction may be associated with vaginal shortening, vaginal tightening, and vaginal pain. The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

The FDA convened an Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee on September 8 and 9, 2011. An update on the safety, effectiveness, and risk/benefit of vaginal placement of

surgical mesh for POP repair was discussed. The Panel consensus[2] was that:

- The safety of vaginal mesh intended for POP repair is not well established
- Depending on the compartment, vaginal placement of mesh for POP repair may not be more effective than traditional native-tissue repair without mesh
- The risk/benefit of vaginal placement of mesh for POP repair is not well established

Feedback From Outside Urology

Urogynecology

A well-written commentary by urogynecologists in 2010, prior to the most recent FDA communication, noted that the use of transvaginal mesh in repair of POP and SUI continues to be an excellent option for many patients.[3] The article warned that physicians need to be kept up to date on the lack of long-term data surrounding the use of transvaginal mesh in repair of SUI and POP.

Mucowski and colleagues[3] noted that, in light of the recent US Supreme Court decision in *Riegel v Medtronic Inc.*,[4] and in conjunction with the manufacturer's use of the learned intermediary doctrine to shift liability to physicians, it is now harder for injured patients to sue manufacturers of medical devices. Patients injured from the use of a medical device may be more likely to sue their physicians and claim lack of proper informed consent.

The authors noted that the current legal environment should not deter physicians from offering mesh repair for POP and SUI to those patients who may best benefit. Physicians should properly obtain and document informed consent prior to offering and performing transvaginal mesh repairs.[3]

Media

In 2011, Voreacos and Nussbaum reported that the media has focused on the lawsuits and case studies involved with the pelvic floor mesh.[5] The FDA notification brought it to the attention of lawyers who were not aware of this issue previously. None of the cases have gone to trial and women must prove their claims that mesh makers knew that the products were defective and of the safety risks but failed to disclose them. Makers of mesh, including Johnson & Johnson (J&J; New Brunswick, NJ), Boston Scientific (Natick, MA), Bard (Murray Hill, NJ), and American Medical Systems (Minnetonka, MN), told the FDA advisory panel in September 2011 that using mesh in transvaginal procedures is safe and effective and serious injuries are rare. J&J stated that it may be too early to comment on the potential impact of mesh lawsuits, but that the company is willing to conduct studies of the devices to ensure doctors and patients have "informed access to treatment options."[5]

Lawyers

Lawyers specializing in mesh cases are offering free case reviews since the FDA's warning. One Web site, pelvicmeshlawyers.com, claims that between 2008 and 2010, the number of pelvic mesh complaints tripled over the preceding 3 years, half of which were the result of failed POP repair.[6] This Web site offers comprehensive information about vaginal mesh including when it was known that transvaginal implantation of mesh was harmful and where to find details about the FDA transvaginal mesh warning as well as patients' rights.[6] It also notes that these lawyers will work to recover lost wages, pay for medical bills, and compensate for the pain associated with vaginal mesh problems. ■

References

1. US Food and Drug Administration. Urogynecologic surgical mesh: update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse. July 2011. www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf. Accessed February 28, 2012.
2. Obstetrics & Gynecology Devices Panel. Surgical mesh repair of pelvic organ prolapse (POP), September 8-9, 2011. www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM271769.pdf. Accessed February 28, 2012.
3. Mucowski SJ, Jurnalov C, Phelps JY. Use of vaginal mesh in the face of recent FDA warnings and litigation. *Am J Obstet Gynecol*. 2010;203:103.e1-e4.
4. *Riegel v Medtronic Inc.*, 552 US, 312 (2008).
5. Voreacos D, Nussbaum A. The next medical device controversy: vaginal mesh. *Business Week*. September 15, 2011. www.businessweek.com/magazine/the-next-medical-device-controversy-vaginal-mesh-09152011.html. Accessed February 28, 2012.
6. Onder, Shelton, O'Leary & Peterson, LLC/Pelvic Mesh Lawyers. Surgical Mesh Lawyers offer free case review after FDA issues warning regarding serious complications from transvaginal placement of surgical mesh in repair of pelvic organ prolapse. www.pelvicmeshlawyers.com/. Accessed February 28, 2012.

Pediatric Urology

Urodynamics in Children

Ellen Shapiro, MD, FACS, FAAP
New York University School of Medicine, New York, NY
[*Rev Urol*. **2012;14(1/2):36-38 doi: 10.3909/riu0549**]

Drzewiecki and Bauer from Boston Children's Hospital provide a review of urodynamics (UDS) in children.[1] First, a history, physical examination, and a 3-day voiding and bowel diary are obtained. A renal sonogram noting bladder volume, residual volume, and bladder wall thickness is then performed.[2]